UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

LOUISIANA WHOLESALE DRUG CO., INC., On Behalf of Itself and All Others Similarly Situated, Plaintiffs, v. SANOFI-AVENTIS, SANOFI-AVENTIS U.S. LLC, and AVENTIS PHARMACEUTICALS INC., Defendants.	Civil No. 07-cv-7343 (HB) Hon. Harold Baer, U.S.D.J. ECF Case

PLAINTIFF LOUISIANA WHOLESALE DRUG CO., INC.'S MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS SANOFI-AVENTIS US LLC AND AVENTIS PHARMACEUTICALS, INC.'S MOTION TO DISMISS THE COMPLAINT FOR FAILURE TO STATE A CLAIM

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INTRODUCTION

Defendants sanofi-aventis us llc and Aventis Pharmaceuticals, Inc. ("Defendants") move to dismiss the Class Action Complaint ("Cpt.") of Plaintiff Louisiana Wholesale Drug Co., Inc. ("Plaintiff" or "Louisiana Wholesale") on three separate bases, each of which is without merit.

First, Defendants argue that Defendants' Citizen Petition (the "Petition") cannot be deemed a "sham" as a matter of law, because the Food and Drug Administration ("FDA") granted the relief that Defendants sought in their Petition. As detailed below, Defendants' argument completely mischaracterizes both the relief sought in, and the FDA's complete denial of, the Petition. Contrary to Defendants' characterization of their Petition as successful,[1] the FDA emphatically rejected the Petition as "**unfounded**," declaring, without qualification, that the "**Petition is denied.**" Cpt. Ex. 1 at 7, 8 (emphasis added).

Defendants claim that their Petition asked the FDA to require multiple generic manufacturers - - who each had filed an Abbreviated New Drug Application ("ANDA") seeking FDA approval to sell generic versions of Defendants' brand name leflunomide drug, Arava, in 10 mg and 20 mg strengths - - to include, in their labeling, reference to a 100 mg loading dose that was recommended in Arava's labeling. Defendants further claim that the FDA granted this request when it stated: "In light of the discussion above, FDA will require the labeling for generic leflunomide products to include the labeling approved for the [branded drug], Arava, concerning the use of a 100-mg loading dose." *See* MTD at 5, 11-12.

The Petition, however, did not request that the generics' labeling include reference to a 100 mg loading dose. Rather, the Petition requested that the FDA not approve any generic leflunomide product unless the generic manufacturers also sought approval for (1) their ***own***

[1] *See* Defendants' Motion to Dismiss ("MTD") at 11-12, 15.

generic 100 mg tablet or (2) demonstrated bioequivalence between five 20 mg tablets (to be used as a loading dose) and one 100 mg tablet. In other words, Defendants specifically argued that the generics should ***not*** be allowed to refer to a 100 mg loading dose, nor be approved, unless one of these conditions was met. Thus, when the FDA stated that the generics' labeling could and would make reference to a 100 mg loading dose, and approved each of the ANDAs on the same date it denied Defendants' Petition - - ***without requiring the generics to seek and obtain approval for their own generic loading dose in the form of a 100 mg tablet or five 20 mg tablets*** - - this was the exact result that Defendants argued strenuously against.

Defendants nonetheless seek to take credit for the FDA's conclusion that it was requiring reference to a 100 mg loading dose "[i]n light of the discussion above." However, Defendants do not inform the Court that the "discussion above" -- referring to the seven-page discussion in the FDA's response to Defendants' Petition - - was a complete repudiation of Defendants' Petition, and included the FDA's statements that:

- the entire basis of Defendants' Petition - - that the generics had to first seek and obtain approval for their own 100 mg loading dose (or prove that five 20 mg tablets were bioequivalent to one 100 mg Arava tablet), in order to obtain approval for their 10 mg and 20 mg doses - - was a "false premise," *see* Cpt. Ex. 1 at 6; and

- Defendants' belief that the generic manufacturers were seeking to omit any mention of the 100 mg loading dose (or seeking to replace it with five 20 mg tablets) was "incorrect[] specul[ation]." *Id.*

Moreover, the FDA's "discussion" made it clear that the generics did not have to obtain approval for their own 100 mg loading dose in order to receive approval for 10 mg and 20 mg tablets, because the FDA routinely permits companies to refer in their labeling to dosage strengths and/or products made by different manufacturers. *Id.* Indeed, Defendants were well aware of this common practice, since the labeling of two of their own approved drugs refers to products made

only by other manufacturers. FDA also noted that Defendants offered no reason why the FDA should not follow this common practice in the case of generic Arava. *Id.*

There is no basis to disregard Plaintiff's clear and specific allegations that the Petition was objectively baseless. *See* Cpt at ¶¶ 7, 52-61. Defendants attempt to substitute their own self-serving (and incorrect) interpretation of the facts for Plaintiff's allegations (which must be taken as true). *See, e.g.*, MTD at 15. At best, Defendants have raised a factual dispute that cannot be resolved on a motion to dismiss.

Second, Defendants argue that Louisiana Wholesale lacks standing because any delay in FDA approval of the generic versions of Arava was necessarily caused by the governing statutory and regulatory scheme, not by Defendants' sham Petition. This is no more than a transparent attempt to blame Congress and the FDA for Defendants' own conscious decision to game the statutory and regulatory system by filing a Petition they knew was baseless, but nevertheless would (and did) delay FDA approval of generics. *See* Section II(A) below.

Defendants also contend that Louisiana Wholesale, a direct purchaser of Arava from Defendants, lacks standing to pursue its claim for overcharges because the generic manufacturers would be more efficient enforcers of the antitrust laws. In light of decades of Supreme Court and Second Circuit authority holding that direct purchasers have standing to pursue overcharge damages, this argument is frivolous. *See* Section II(B) below.

Third, Defendants argue that Plaintiff's Complaint must be dismissed because the relevant market alleged by Plaintiff - - Arava and its AB-rated generic equivalents - - is implausible. As set forth in Section III below, Defendants are wrong because: (a) Louisiana Wholesale has alleged the existence of direct proof of monopoly power (*i.e.*, the power to control prices or exclude competition), which obviates the need to prove monopoly power indirectly by

defining a relevant market; (b) if Louisiana Wholesale must allege a relevant market, courts have routinely accepted the market alleged here - - a brand name drug and its generic equivalents - - in cases alleging delayed generic competition; and (c) as this Court has recognized, the scope of the relevant market is an inherently factual question that cannot be resolved on a motion to dismiss.

FACTUAL BACKGROUND

A. The FDA Recognizes That Brand Manufacturers Often Use Citizen Petitions to Delay FDA Approval of Generic Drugs

Any person or entity, including a pharmaceutical manufacturer, may file a Citizen Petition, requesting that the FDA take, or refrain from taking, administrative action, including that the FDA not approve an ANDA. Cpt. ¶ 35. Although the Citizen Petition process is intended to provide an opportunity to express genuine legal or scientific concerns about a product, in recent years some brand name pharmaceutical manufacturers have abused the process as a tactic to extend their monopolies on certain brand name drugs. *Id.* ¶¶ 35, 38.

Specifically, because it is the practice of the FDA, well known in the pharmaceutical industry, to consider and respond to a Citizen Petition prior to approving any pending ANDA that is the subject of the petition, branded manufacturers often file Citizen Petitions on the eve of FDA approval of ANDAs for competing generic drugs, in an attempt to extend the branded companies' marketing exclusivity. *Id.* ¶ 38, 42. Thus, Citizen Petitions, even if (as here) utterly meritless, may delay FDA approval of pending ANDAs while the FDA evaluates the Citizen Petition. *Id.* ¶ 38. FDA Chief Counsel Sheldon Bradshaw acknowledged these abuses just days after the agency denied Defendants' Petition, citing:

> several examples of Citizen Petitions that appear designed not to raise timely concerns with respect to the legality or scientific soundness of approving a drug application but rather to try to delay the approval simply by compelling the agency to take the time to consider arguments raised in the petition whatever the merits and regardless of whether or not the petitioner could have made those very arguments months and months before.

See id. ¶ 40.

B. Plaintiff Alleges That Defendants' Unlawful Scheme Delayed AB-rated Generic Competition for Arava

Defendants' Arava NDA

The FDA approved Defendants' New Drug Application ("NDA") for Arava (leflunomide) on September 10, 1998, in strengths of 10 mg, 20 mg and 100 mg. The typical daily dose of Arava is 20 mg. *Id.* ¶ 44. Arava's approved labeling recommends the use of a "loading dose" of 100 mg per day for three days. The loading dose is not essential to the effective use of the product, and elimination of the loading dose may actually decrease the risk of adverse events for some patients. *Id.* ¶ 35.

As filer of the Arava NDA, Defendants enjoyed the exclusive right to market Arava in all dosage forms for five years, with an additional six months "pediatric exclusivity." *Id.* ¶ 46. Defendants were aware: (1) that under the Hatch-Waxman Act,[2] no generic manufacturer could file an ANDA seeking FDA approval for an AB-rated generic version of Arava until March 10, 2004 (five years and six months after NDA approval), (2) that generic leflunomide ANDAs would be filed on or about March 10, 2004, and (3) of the approximate time it takes the FDA to approve ANDAs. *Id.* ¶¶ 46-47, 50. Thus, Defendants knew that, if they did nothing, they would likely face generic competition in or about March or April 2005.

[2] The Hatch Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984), amended the Federal Food, Drug and Cosmetics Act (21 U.S.C. §§ 301-392) ("FDCA"). Cpt. ¶ 25. The Act was designed to (1) speed the approval of generic drugs by permitting generic manufacturers to file an ANDA, in which the generic applicant relies on the FDA's previous determination, under the brand drug's NDA, that the drug is safe and effective, and (2) protect the incentive of pharmaceutical manufacturers to create new products by, among other things, providing to brand name manufacturers several potential periods of marketing exclusivity, during which time the brand manufacturers possess legitimate protection from generic competition. *Id.* ¶¶ 25-31.

Defendants Stopped Selling the 100 mg Tablet as a Pretext for Impeding Generics

In September 2002, Defendants stopped selling the 100 mg loading dose of Arava. *Id.* ¶ 48. Instead, Defendants supplied the loading dose as a free sample to doctors. *Id.* By providing the loading dose for free, Defendants disincentivized any generic manufacturer from seeking approval to sell the 100 mg tablet. This also provided a pretext for Defendants to delay generic entry by filing a Petition asking FDA not to approve the ANDAs unless each generic sought approval for their own 100 mg dose (or proved that five 20 mg tablets were bioequivalent to Arava's 100 mg dose). *Id.* ¶ 49.

Defendants Filed An Objectively Baseless Citizen Petition

As Defendants expected, on or about March 10, 2004, five generic manufacturers filed ANDAs seeking FDA approval to market AB-rated generic versions of 10 mg and 20 mg leflunomide tablets. *Id.* ¶ 51.

On March 31, 2005, when FDA approval of the leflunomide ANDAs was imminent, Defendants filed their Petition, requesting that FDA withhold approval of any leflunomide ANDA that "(1) does not seek approval of a 100 mg leflunomide tablet that is bioequivalent to Arava 100 mg or (2) does not establish *in vivo* bioequivalence between five 20 mg leflunomide tablets and one Arava 100 mg tablet." *Id.* ¶ 52; Cpt. Ex. 2 at 1. The essence of Defendants' Petition was that all generics should have to seek approval of ***their own*** loading doses, in either one 100 mg tablet or five 20 mg tablets, in order to obtain approval of their 10 mg and 20 mg doses.

On September 13, 2005, the FDA predictably denied Defendants' Petition in its entirety, and approved the ANDAs. *See* Cpt. Ex. 1 at 1, 8; Cpt. ¶ 62. In so doing, the FDA emphatically rejected each of the arguments in Defendants' Petition, and refused to grant any of

the relief Defendants requested. Specifically, the FDA found that:

- nothing in the FDCA or FDA regulations required the leflunomide ANDAs to seek approval for all dosage strengths of Arava, including the 100 mg loading dose. In fact, FDA cited 13 prior examples where it had approved ANDAs that did not seek approval for all dosage strengths sold by the corresponding brand company. Cpt. Ex. 1 at 7.

- Defendants offered "no reasoned basis" to accept, and "no explanation" supporting, their argument that the ANDAs could not be approved because the FDA should not permit the generic manufacturers to reference a 100 mg loading dose in their labels without first seeking and obtaining approval to sell a loading dose. *Id.* at 6. To the contrary, FDA explained that it was "not uncommon" for approved labels to refer to products that the applicant did not manufacture; indeed, FDA cited as examples two of Defendants' products where the approved label referenced products manufactured by other companies. *Id.* at 7.

- Defendants' argument that the generic sponsors might attempt to omit all references to a 100 mg loading dose from the generic labels was "incorrect speculation." Cpt. Ex. 1 at 6.

Thus, the FDA denied Defendants' Petition, and characterized it as "unfounded." *Id.* at 7.

Defendants' Scheme Delayed Generic Competition

Defendants filed their Petition for the express purpose of delaying FDA approval of all five generic leflunomide ANDAs. Cpt. ¶ 5. Defendants filed their Petition on the eve of FDA approval of the ANDAs. *Id.* at ¶¶ 7, 54. That is because Defendants knew that, due to the FDA's limited resources and its practice of carefully considering all Citizen Petitions, the mere filing of its Petition, though meritless, would nevertheless delay FDA approval of each leflunomide ANDA. *Id.* ¶ 6, 42. That is exactly what occurred. Although the FDA found the Petition to be completely unfounded, it did not approve the leflunomide ANDAs until the same date that it denied the Petition. If the Petition had not been filed, the ANDAs would have been approved (and on the market) months earlier. *Id.* ¶ 7, 62. As a result of Defendants' unlawful conduct, Plaintiff and the Class were denied the opportunity to purchase lower-priced generic versions of Arava, and were forced to pay higher prices for branded Arava. *Id.* ¶ 64.

ARGUMENT

I. PLAINTIFF'S SHAM PETITIONING CLAIM SHOULD NOT BE DISMISSED

A. Applicable Legal Standards

On a motion to dismiss, the Court must accept all well-pled factual allegations as true, and draw all reasonable inferences in the non-movant's favor. *In re Xethanol Corp. Sec. Litig.*, 2007 U.S. Dist. LEXIS 65935, *5 (S.D.N.Y. Sept. 7, 2007) (Baer, J.); *Brown v. Austin*, 2007 U.S. Dist. LEXIS 74178 (S.D.N.Y. Oct. 4, 2007). A plaintiff need only "provide the 'grounds upon which his claim rests through factual allegations sufficient to raise a right to relief above the speculative level on the assumption that all the allegations in the complaint are true (even if doubtful in fact).'" *Id.* (quoting *Bell Atlantic v. Twombly*, 127 S. Ct. 1955, 1964-65 (2007)).

The *Noerr-Pennington* doctrine[3] shields genuine petitioning activity, not sham petitioning, from antitrust liability. *See, e.g.*, *New York Jets LLC v. Cablevision Systems Corp.*, 2005 U.S. Dist. LEXIS 23763, *21 (S.D.N.Y. Oct. 17, 2005) (Baer, J.); *In re Buspirone Antitrust Litig.*, 185 F.Supp.363, 368 (S.D.N.Y. 2002) (Koeltl, J.). "Sham" petitioning activity is conduct designed to "use the governmental *process* - - as opposed to the *outcome* of that process - - as an anticompetitive weapon.'" *New York Jets LLC*, 2005 U.S. Dist. LEXIS 23763, *20 (quoting *City of Colum. v. Omni Outdoor Adver., Inc.*, 499 U.S. 365, 380 (1991)) (emphasis in original). *See also Litton Sys., Inc. v. AT&T Co.*, 700 F.2d 785, 812 (2d Cir. 1983) (conduct that "was not undertaken" to influence governmental action, "but in the hope of delaying it," is a sham).

In *Professional Real Estate Inv's Inc. v. Columbia Pictures Indus. Inc.*, 508 U.S. 49, 60-61 (1993) ("*PRE*"), the Supreme Court established a two-pronged standard for meeting the

[3] *See Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508 (1972); *United Mine Workers of Am. v. Pennington*, 381 U.S. 657 (1965); *E.R.R. Presidents Conf. v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961); *United Mine Workers of Am. v. Pennington*, 381 U.S. 657 (1965).

"sham" exception to the *Noerr-Pennington* rule: (1) the "objective" prong - - the petitioning activity must be "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits"; and (2) the "subjective" prong - - the "baseless" petitioning activity "reveals an attempt to interfere directly with the business relationships of a competitor through the use [of] the governmental process - - as opposed to the outcome of that process - - as an anticompetitive weapon." *See also Primetime 24 Joint Venture v. National Broadcasting Co.*, 219 F.3d 92, 100-101 (2d Cir. 2000); *New York Jets*, 2005 U.S. Dist. LEXIS 23763, *29-30. Because Defendants here have moved to dismiss Plaintiff's Complaint only on objective baselessness grounds, Plaintiff will focus here on its allegations related to the objective prong.

In assessing whether a "reasonable litigant could realistically expect success on the merits" under the objective prong, the *PRE* Court adopted the theory of probable cause, "as it is understood and applied in the common-law tort of wrongful civil proceedings." *PRE*, 508 U.S. at 62. Thus, an antitrust plaintiff must demonstrate that the petitioner did not possess a reasonable belief that its claim would be held valid upon adjudication. *Id.*

Whether a particular petitioner possessed such a reasonable belief is a question of fact that cannot be decided on a motion to dismiss where, as here, there are factual disputes regarding the underlying facts and/or defendants' knowledge of those facts. *See id.* at 63; *In re Relafen Antitrust Litig.*, 346 F.Supp.2d 349, 362 (D. Mass. 2004) (because the parties disputed the facts related to defendants' knowledge at the time of the filing, the court was "duty-bound" to submit the probable cause issue to a jury). *See also New York Jets, LLC v. Cablevision Sys. Corp.*, 2005 U.S. Dist LEXIS 33362, *6-7 (S.D.N.Y. Dec. 14, 2005) (Baer, J.) (where there are issues of disputed fact, such issues cannot be decided without the benefit of full discovery).

B. Plaintiff Has Alleged that Defendants' Petition Was Objectively Baseless

Plaintiff expressly alleges that the filing of Defendants' Petition was "objectively baseless (*i.e.*, sham)." *See, e.g.*, Cpt. ¶15. Plaintiff also alleges facts and circumstances supporting that allegation, including that: (a) Defendants knew that the ANDA sponsors could refer to a 100 mg loading dose in their labeling without seeking approval for their own loading dose (*id.* at ¶ 58); (b) Defendants had no basis to believe that any generic applicant was seeking to omit altogether a reference to a loading dose, or seeking to refer to a loading dose of five 20 mg tablets in its label (*id.* at ¶ 57); and (c) no reasonable pharmaceutical manufacturer could have expected the Petition to succeed on the merits, in light of the applicable law, regulations, and FDA practices - - all of which a reasonable pharmaceutical manufacturer with experience in the industry would have known were contrary to the positions set forth in Defendants' Petition. *Id.* at ¶¶ 57-61.

Based on these facts, Plaintiff has adequately alleged that Defendants lacked the probable cause necessary to file the Petition. *See ICOS Vision Sys. Corp., N.V. v. Scanner Technologies Corp.*, 2006 U.S. Dist. LEXIS 13847, *14 (S.D.N.Y. Mar. 29, 2006) (if, as plaintiff alleged, the petitioner knew that patent infringement damages statute that it used to threaten plaintiff's customers did not apply, then the petitioner's litigation threats were not objectively reasonable); *Moore U.S.A. Inc. v. The Standard Register Co.*, 139 F.Supp.2d 348, 359 (W.D.N.Y. 2001); *Jarrow Formulas, Inc. v. Int'l. Nutrition Co.*, 175 F.Supp.2d 296, 311 (D. Conn. 2001).

Defendants admit that Louisiana Wholesale has alleged that the Petition was objectively baseless, but ask the Court to disregard these allegations as "conclusory." *See* MTD at 1. As shown above, Plaintiff has alleged facts, not merely conclusions. Defendants' contrary claim is a

transparent effort to impermissibly substitute their own interpretation of the facts for Plaintiff's. Such factual disputes cannot be resolved on a motion to dismiss.

C. The FDA Denied the Relief Defendants Requested

Defendants argue that their Petition indisputably had merit because it was successful. *See* MTD at 10-12, 15. This argument blatantly mischaracterizes both the relief requested in, and the FDA's denial of, the Petition.

Defendants argue that the Petition's merit is demonstrated by the fact that (1) Defendants requested in their Petition that the generics not be permitted to omit references to a 100 mg loading dose, and (2) the FDA's seven page response to Defendants' arguments concludes with the statement that, "[i]n light of the discussion above, the FDA will require the labeling for generic leflunomide products" to reference a 100 mg loading dose. *Id.* at 15-16.

Defendants ***did not*** ask the FDA to require generic manufacturers to include a reference to Arava's 100 mg loading dose in their labeling, as Defendants now claim. Defendants' Petition actually requested "that the agency withhold final approval of any ANDA that (1) does not seek approval of a 100 mg leflunomide tablet that is bioequivalent to Arava 100 mg or (2) does not establish in vivo bioequivalence between five 20 mg leflunomide tablets and one Arava tablet." Cpt. Ex. 2 at 1; Cpt. ¶ 55. In other words, Defendants' unsupported position was that the generic sponsors ***could <u>not</u> make reference to a 100 mg loading dose in their labels*** unless they sought and gained approval to make and market ***their own*** loading dose. *See, e.g.*, Defendants' June 10, 2005 Comment to FDA at 3 (attached hereto as Exhibit 1). The FDA's conclusion that the generic sponsors could and would make reference to Defendants' 100 mg loading dose - - ***without*** the need to seek approval to manufacture and sell ***their own*** loading dose - - was the exact result that Defendants argued against. Therefore, Defendants' after-the-fact attempt to

reconfigure their Petition to match the FDA's statements is a transparent attempt to concoct an objectively reasonable basis for their "unfounded" Petition, and should be rejected.

Moreover, Defendants have made recent admissions that support Louisiana Wholesale's allegations that the Petition was objectively baseless. In a recent letter to this Court, Defendants admitted that a "reasonable litigant would certainly expect the FDA . . . to require[] reference to a 100 mg loading dose" in the generics' label. *See* October 3, 2007 Letter from Julia E. McEvoy to The Honorable Harold Baer, Jr. at 4 (attached hereto as Exhibit 2). Yet, in its Petition, Defendants argued that the generics could ***not*** make reference to the 100 mg loading dose, unless and until they first sought and obtained approval to manufacture and sell their own version of the loading dose. Thus, by its own recent admission, Defendants' position to FDA was contrary to what any "reasonable litigant would certainly expect the FDA" to do, *i.e.*, allow and even require the labels of the generics to reference the loading dose.

Defendants also rely heavily on the fact that the FDA prefaced its statement that the generics had to reference a 100 mg loading dose in their labels with the phrase "in light of the discussion above." *See, e.g.*, MTD at 5, 15. Defendants claim that, because the FDA's "discussion" was prompted by Defendants' Petition, the FDA's statement that the generics had to reference a 100 mg dose indicated the FDA's agreement with the Petition. This simplistic sophistry is belied by the fact that the actual "discussion" referenced by the FDA was the agency's systematic rejection of each of Defendants' arguments and requests for action: (a) "there is nothing in the Act or the regulations that requires an ANDA applicant to seek approval for all available strengths of the [branded drug]" (Cpt. Ex. 1 at 7); (b) "[i]t is not unusual for an ANDA applicant to decline to seek approval for certain strengths approved for the [branded drug]," naming as examples 13 different products (*id.*); (c) "[t]here is no requirement for an

ANDA sponsor to demonstrate equivalence between different strengths of its own product line" (*id.* at 4); (d) labeling for generic leflunomide products approved in 10 mg and 20 mg strengths may reference a 100 mg loading dose that the generic sponsors did not produce (*id.*) and Defendants provided no "reasoned," or any, explanation, for petitioning to the contrary, (*id.* at 6 n.14); and (e) it is "not uncommon" for the labeling of products to refer to other drugs not provided by the sponsor, naming as examples two products produced by Defendants (*id.* at 7; Cpt. ¶ 60 n.3). Based on *this* discussion, which rejected Defendants' arguments and requests, the FDA found that Defendants' Petition was "unfounded," and denied it as to all five ANDAs. *Id.* [4]

Thus, Defendants' claim that their Petition had merit, because it actually succeeded, clearly fails. The Petition was a complete failure, and Defendants' tortured arguments to the contrary raise, at best, issues of fact that cannot be resolved on a motion to dismiss.

Defendants, citing *Potters Medical Center v. City Hosp. Ass'n*, 800 F.2d 568 (6th Cir. 1986), claim that their Petition fits within a supposed blanket rule that a petition has objective

[4] Defendants imply that their Petition was successful as to one generic, Kali Laboratories, because Kali's objection to the Petition supposedly implies that Kali's ANDA asked FDA to approve a label without reference to any loading dose. MTD at 14. This argument fails for at least two reasons. First, Plaintiff disputes Defendants' interpretation of Kali's objection (based, *inter alia*, on FDA's conclusion that Defendants' contention that the generics were seeking approval of labels that did not reference a loading dose was "incorrect speculation"). The actual content and context of Kali's ANDA cannot be determined without discovery. Second, even if one assumes *arguendo* that Kali had in fact requested approval of its ANDA without referencing any loading dose, as Defendants speculate, that would not mean that Defendants had an objectively reasonable basis for their Petition. Defendants admit that they did not know what was in any of the five pending ANDAs, let alone all of those ANDAs, when it filed its Petition. Yet it filed a Petition that was indiscriminately directed at each of those ANDAs. Thus, the Petition is effectively a series of petitions against each ANDA. The Second Circuit has expressly held that, "in cases in which the defendant is accused of bringing a whole series of legal proceedings" for the purpose of harassing or impeding competitors, "it is immaterial that some of the claims might, 'as a matter of chance,' have merit. The relevant issue is whether the legal challenges 'are brought pursuant to a policy of starting legal proceedings without regard to the merits and for the purpose of injuring a market rival.'" *Primetime 24 Joint Venture*, 219 F.3d at 101 (quoting *USS-POSCO Indus. v. Contra Costa County Bldg. & Constr. Trades Councel, AFL-CIO*, 31 F.3d 800, 811 (9th Cir. 1994)).

merit if it merely seeks to hold an entity to the same regulatory rules to which the petitioner was held. MTD at 10, 12. *Potters* creates no such blanket rule. It simply held (based on a summary judgment record) that, *under the facts of that case* - - which, unlike this case, were undisputed - - the petition clearly had merit. *Potters* is inapplicable here, however, because the undisputed facts in *Potters* included that: (1) the government had asked the defendant to file the challenged petition; (2) numerous other hospitals made comments similar to defendants'; and (3) multiple government agencies adopted defendants' position. Here, by contrast, Defendants' Petition was unsolicited, uncorroborated and completely unsuccessful.[5]

Moreover, even if there was a general rule immunizing petitions that merely ask governmental bodies to follow their existing regulations (and to be clear, there is no such rule), Defendants' Petition would not fall within that rule. The Petition did not ask FDA to require the leflunomide ANDA filers to follow the same rules as Defendants followed; to the contrary, as detailed above, the Petition asked FDA to force the generics to manufacture their own loading dose in order to obtain approval of their 10 mg and 20 mg doses - - even though FDA's established practice was to allow manufacturers, including Defendants, to reference approved doses or products that they did not manufacture.[6]

[5] The other cases cited by Defendants are also distinguishable since, in each of those cases, the defendants' petitioning activity enjoyed *Noerr-Pennington* immunity because the administrative agency had adopted the defendant's stated position.

[6] Defendants' claim that the Petition merely asked FDA to apply its rules in an evenhanded manner ignores the fact that NDAs and ANDAs are subject to different requirements; *e.g.*, brand name companies must establish safety and efficacy for each and every milligram strength of a product at issue in the NDA, whereas generic companies are free to seek and obtain approval for less than all milligram strengths of a product sold by the corresponding branded company.

II. PLAINTIFF HAS STANDING TO PURSUE ITS CLAIMS

A. Plaintiff Has Sufficiently Alleged that Defendants' Conduct Delayed FDA Approval of Multiple Versions of Generic Arava

Defendants' assertion that Plaintiff has failed to allege any injury traceable to Defendants' conduct completely disregards Plaintiff's allegations that: (a) Defendants knew that the filing of a Citizen Petition, even if frivolous, would delay approval of the generic leflunomide ANDAs because of FDA's well-known practice of considering and responding to such petitions before approving an ANDA, Cpt. ¶¶ 6, 42; (b) Defendants purposefully timed the filing of its Petition to delay ANDA approvals, *id.* ¶¶ 7, 54; Cpt. Ex. 1 at 3 n.6;[7] and (c) the Petition in fact delayed such approvals. Cpt. ¶¶ 7, 62.

Defendants ask the Court to disregard these allegations because, according to Defendants, 21 C.F.R. § 10.35(d) prohibits citizen petitions from delaying the FDA's approval of generic drugs. This is not (and cannot be) correct; if filing a citizen petition could not possibly delay generic approval, FDA Chief Counsel Bradshaw would not have stated publicly that brand name pharmaceutical manufacturers have misused citizen petitions "to try to delay the approval [of generic drugs] simply by compelling the agency to take the time to consider the arguments raised in the petition whatever the merits . . . ." *See* Cpt. ¶ 40. Further, Defendants fail to cite the language in § 10.35(d), which permits stays of approval if "one of the following applies: (1) the Commissioner determines that a stay or delay is in the public interest and stays the action." Chief Counsel Bradshaw's comments reflect the actual practice of the Commissioner, pursuant to his discretion under subsection (d), to resolve all pending citizen petitions before approving the pending ANDA. *See, e.g.*, Complaint ¶¶ 38, 42. *See also* 64 Federal Register 66822, p.

[7] The FDA specifically noted that "the majority of the citations in [Defendants'] Petition are many years old, and were available to Aventis well before the petition was submitted." Cpt. Ex. 1 at 3, n.6.

66822-23 ("Reviewing and responding to these petitions can also be, and often is, a resource-intensive and time-consuming task because FDA **must** research the petition's subject, examine scientific, medical, legal, and sometimes economic issues, and coordinate internal agency review and clearance of the petition response. . . .") (emphasis added).[8]

Finally, Defendants imply that problems with the ANDAs - - and not the Petition - - delayed approval of generic versions of Arava. This argument is based entirely on the fact that the ANDA approval letters reference the date of certain amendments to the ANDAs that occurred after the Petition. MTD at 17. Even if the Court were to consider these letters, the mere existence of these amendments does not mean that these amendments caused all - - or any - - of the delay allegedly caused by the Petition.[9] Absent discovery, there is no evidence whatsoever regarding the nature, scope, timing or purpose of the ANDA amendments. In Plaintiff's counsel's experience litigating many pharmaceutical antitrust cases, amendments to ANDAs are common up until, and even after, the date of FDA approval. Such amendments often do not cause or require any delay in obtaining FDA approval. Many such pre-approval amendments can be made as "post-approval supplements" that do not impede the approval, manufacturing, marketing or sale of a product. Thus, the bare fact that ANDA amendments were made after the

[8] Defendants' citation to cases where it was definitively established that the relevant existing laws in fact excluded competitors (MTD at 17-18) are inapplicable here, because Defendants cite no law that excluded generic versions of Arava.

[9] In deciding a Rule 12(b)(6) motion, courts must limit their analysis to facts that appear on the face of the complaint, exhibits attached to the complaint or incorporated by reference, and matters that may be judicially noticed. *See, e.g,, Halpert Enterprises, Inc. v. Harrison*, 2007 U.S. Dist. LEXIS 9729, *11 (S.D.N.Y. Feb. 14, 2007) (Baer, J.). Therefore, the Court's consideration of the ANDA amendments mentioned in the approval letters would be improper. Plaintiff's mere citation of the ANDA approval dates does not "incorporate by reference" any documents related to the FDA's review and approval of those ANDAs. In addition, while the ANDA approval letters may be a matter of public record, the various amendments mentioned therein are not.

filing of the Petition says nothing about whether, and for how long, Defendants' Petition delayed FDA approval of the ANDAs. At most, the amendments may raise issues of fact that cannot be decided without affording Plaintiff an opportunity to conduct discovery.

B. Forty Years of Antitrust Jurisprudence Confirms That Plaintiff is the Preferred Party to Seek Overcharge Damages

Since the Supreme Court's decisions in *Hanover Shoe, Inc. v. United Shoe Machinery Corp.*, 392 U.S. 481, 493-494 (1968) and *Illinois Brick Co. v. Illinois*, 431 U.S. 720, 746 (1977), it has been clear that direct purchasers have standing to bring antitrust overcharge claims. *Illinois Brick Co.* 431 U.S. at 746 (denying **in**direct purchasers standing to assert overcharge antitrust claims). *See also Berkey Photo Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 294 (2d Cir. 1979) ("Where a monopolist has acquired or maintained its power by anticompetitive conduct. . . a direct purchaser may recover the overcharge caused by the violation.") (citations omitted). That is because direct purchasers are the "group . . . most likely to press their claims with the vigor that the § 4 treble-damages remedy was intended to promote." *BlueShield of Virginia v. McCready*, 457 U.S. 465, 474 (1982).

Ignoring this controlling law, Defendants argue that Louisiana Wholesale lacks standing because the generic manufacturers were more directly harmed by Defendants' conduct. *See* MTD at 19. But Defendants do not (and cannot) cite a single case holding that direct purchasers lose their standing to pursue overcharge damages, simply because competitors may also have been impacted by defendants' anticompetitive conduct. To the contrary, courts have regularly upheld claims brought by direct purchasers alleging that generic entry has been delayed through sham litigation or other anticompetitive conduct, even where the unlawful conduct may also have impacted generic manufacturers. *See, e.g., In re Tricor Direct Purchaser Antitrust Litig.*, 432 F.Supp.2d 408, 425 (D. Del. 2006); *In re Relafen Antitrust Litig.*¸ 218 F.R.D. 337, 344 (D. Mass.

2003); *In re Buspirone Patent & Antitrust Litig.*, 210 F.R.D. 43 (S.D.N.Y. 2002); *In re Cardizem CD Antitrust Litig.*, 200 F.R.D. 297 (E.D. Mich. 2001).[10]

Defendants argue that Plaintiff is not an "appropriate and efficient enforcer of the antitrust laws" because it cannot satisfy any of the four factors outlined in *Volvo Am. Corp. v. Men's Int'l Prof'l Tennis Council*, 852 F.2d 55, 66 (2d Cir. 1988). MTD at 18-20. However, Plaintiff easily satisfies each of the *Volvo* factors: (1) Plaintiff, and the class of purchasers it seeks to represent, are *direct* purchasers of Arava from Defendants; (2) direct purchasers can be readily identified from Defendants' own sales data and, as the Supreme Court has recognized, belong to a class of plaintiffs that will pursue antitrust enforcement with vigor;[11] (3) the overcharge injury suffered by Plaintiff and the class is easily ascertainable through standard statistical techniques;[12] and (4) no problem of apportioning damages exists because direct purchasers are the *only* class of plaintiffs that can recover overcharges.[13]

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[10] Defendants' cases are inapposite because they involved indirect purchasers. *See Paycom Billing Services Inc. v. Mastercard Int'l Inc.*, 467 F.3d 283, 291 (2d Cir. 2006) (plaintiff lacked antitrust standing because it was "in a position analogous to the indirect purchasers in *Illinois Brick*"); *Laborers Local 17 Health and Benefit Fund v. Philip Morris Inc.*, 191 F.3d 229, 244 (2d Cir. 1999) (health benefit providers alleged injuries from defendants' misrepresentations that caused plaintiffs' subscribers to smoke more, adversely affecting their health, for which the plaintiffs paid out more in health benefits; such injuries were wholly derivative of their subscribers' injuries, and therefore too remote to confer standing).

[11] *See BlueShield of Virginia*, 457 U.S. at 474.

[12] *See e.g.*, *Relafen*, 218 F.R.D. at 344 ("Overcharges, the 'difference between the actual price and the presumed competitive price multiplied by the quantity purchased,' provide what the Supreme Court has long recognized as the principal measure of damages for plaintiffs injured as customers, rather than as competitors."). *See also Cardizem*, 200 F.R.D. at 324 ("standard statistical techniques" can be used to determine damages); *Buspirone*, 210 F.R.D. at 50-51.

[13] Any injury the generics suffered is separate and apart from the injury suffered by direct purchasers. *See, e.g., In re Lower Lake Erie Iron Ore Antitrust Litig.*, 998 F.2d 1144, 1168 (3d Cir. 1993); *Glaberson v. Comcast Corp.*, 2001 U.S. Dist. LEXIS 62672, *25-26 (E.D. Pa. Aug. 31, 2006).

III. PLAINTIFF HAS SUFFICIENTLY ALLEGED MONOPOLY POWER AND A RELEVANT MARKET

Finally, Defendants argue that the relevant market alleged by Plaintiff - - leflunomide and its AB-rated generic equivalents - - is insufficient because, according to Defendants, Plaintiff has failed to adequately address why the relevant market should not include other drugs that are approved to treat rheumatoid arthritis ("RA"). MTD at 20, 23. Defendants are wrong for several reasons.

First, the Supreme Court and the Second Circuit have recognized that, as an alternative to relevant market analysis, pursuant to which monopoly power is proved indirectly, monopoly power can also be proven through direct evidence of the Defendants' ability to control prices and/or exclude competitors. *E.g.*, *FTC v. Indiana Federation of Dentists*, 476 U.S. 447, 460-461 (1986) (relevant market analysis is not required where direct evidence of the anticompetitive effects of the monopoly is available); *Geneva Pharms. Tech. Corp. v. Barr Labs., Inc.* 386 F.3d 485, 500 (2d Cir. 2004); *Tops Mkts, Inc. v. Quality Mkts, Inc.*, 142 F.3d 90, 97-98 (2d Cir. 1998) ("Monopoly power. . .may be proven directly by evidence of control of prices or the exclusion of competition, or it may be inferred from one firm's large percentage share of the relevant market.") (emphasis added). Where direct evidence of monopoly power is available, plaintiffs need not plead or prove monopoly power indirectly, through a traditional relevant market analysis. *PepsiCo, Inc. v. Coca-Cola Co.*, 315 F.3d 101, 107-08 (2d Cir. 2002) ("We agree with PepsiCo that there is authority to support its claim that a relevant market definition is not a necessary component of a monopolization claim"). *See also Broadcom Corp. v. Qualcomm, Inc.*, 2007 U.S. App. LEXIS 21092, *15 (3d Cir. Sept. 4, 2007) ("direct proof of monopoly power does not require a definition of the relevant market"); *In re Schering-Plough Corp.*, 2003

FTC LEXIS 187, *40-42, *46-47 (F.T.C. Dec. 8, 20003), *rev'd on other grounds*, 402 F.3d 1056 (11th Cir. 2005).

Here, Plaintiff has expressly alleged the existence of direct evidence that Defendants maintained the power to control prices of leflunomide by excluding generic competition. Cpt. ¶¶ 73, 75-76, 78-80, 83-86. Specifically, Plaintiff alleges that (1) Defendants excluded generic competition by filing their sham Petition; (2) by excluding the generics, Defendants were able to maintain 100% of leflunomide sales at supracompetitive prices; and (3) once Defendants' exclusion of generics ended, prices for leflunomide plummeted, and Defendants lost virtually all leflunomide sales to the less-expensive generic competitors, due to the well-known downward pressure generics, if not excluded, impose on the purchase price of a drug molecule. *Id.*

Defendants have not even attempted to refute these allegations of monopoly power. But, even if they attempt to do so, such attempts would, at best, raise issues of fact that cannot be decided on a motion to dismiss.

Second, even if Plaintiff were required to plead a relevant market, it has alleged the correct one. "[A] market is properly defined when a hypothetical profit-maximizing firm selling all of the product in that market could charge significantly more than a competitive price, *i.e.*, without losing too many sales to other products to make its price unprofitable." *U.S. v. Visa U.S.A., Inc.*, 163 F. Supp.2d 322, 335 (S.D.N.Y. 2001) ("*Visa*") (citing Department of Justice and Federal Trade Commission, Horizontal Merger Guidelines § 1.11 (1997) (hereinafter "Horizontal Merger Guidelines") (*available at* http://www.usdoj.gov/atr/public/guidelines/hmg.htm)).[14] The market is the "smallest possible group of products" that satisfies

[14] In other words, a "relevant market" is "any grouping of sales whose sellers, if unified by a hypothetical cartel or merger, could profitably raise prices significantly above the competitive level." *AD/SAT, Div. of Skylight, Inc. v. Associated Press*, 181 F.3d 216, 228-29 (2d Cir. 1999).

this test. *New York v. Kraft General Foods, Inc.*, 926 F.Supp. 321, 360 (S.D.N.Y. 1995); Phillip E. Areeda and Herbert Hovenkamp, ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION ("Areeda & Hovenkamp") ¶ 536; Horizontal Merger Guidelines § 1.11.

The relevant market alleged here clearly meets this test. Plaintiff expressly alleges that, during the period that generics were excluded from the market because of Defendants' sham Petition, Defendants were the only firm selling leflunomide, and were able to "impose a significant non-transitory price increase without losing sufficient sales to render the price increase unprofitable." Cpt. ¶¶ 74, 76. In other words, Plaintiff alleges that by excluding generics, Defendants were able to impose artificially-inflated prices on purchasers without losing substantial sales. These allegations, taken as true, sufficiently allege that Defendants would (and did) need to control only branded and AB-rated generic versions of leflunomide (and not any other products) to profitably maintain leflunomide prices significantly above the competitive level that would obtain upon generic entry. *See AD/SAT*, 181 F.3d at 229-29; *Todd v. Exxon Corp.*, 275 F.3d 191, 204 (2d Cir. 2001) (Rule 12 motion denied).

Third, the relevant market must be defined in light of the conduct being challenged. *See* Larner and Nelson, *Market Definition in Cases Involving Branded and Generic Pharmaceuticals, Economics Committee Newsletter*, Vol 7, No. 2 at p. 5 (Fall 2007) ("the proper antitrust market in a case is the market relevant to an analysis of the competitive effects of the alleged behavior.").[15] *See also U.S. Healthcare, Inc. v. Healthsource, Inc.*, 986 F.2d 589, 598 (1st Cir. 1993) (advising courts to ask "what is the antitrust question in this case that market definition aims to answer?"). Here, the conduct being challenged is a scheme by a brand name drug manufacturer to suppress all competition from generic manufacturers of that drug molecule

[15]A copy of the Larner and Nelson article is attached hereto as Exhibit 3.

(not other drug molecules), thereby forcing all purchasers to buy the more expensive brand product. In such cases:

> the proper market for evaluating the competitive effects of such conduct is likely the molecule [*i.e.*, the brand and its generic equivalents], because the alleged anticompetitive effect is suppression of competition between the brand and the generic.

Larner and Nelson, *supra*, at 5. Thus, the proper relevant market here is the market alleged by Plaintiff - - the leflunomide molecule (*i.e.*, branded Arava and its generic equivalents).

Defendants conclusorily assert that a relevant market consisting of a brand and its generic equivalents is too narrow as a matter of law. MTD at 20. But, courts have routinely approved that very relevant market where, as here, the Aantitrust question the market definition aims to answer@[16] relates to the competitive effects of conduct that allegedly suppressed competition between a branded drug and its generic equivalents.[17] *See e.g., In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279, 1319 n. 40 (S.D. Fla. 2005) (AAbbott has power in the relevant market, which is the market for Hytrin and its generic bioequivalent forms of terazosin hydrochloride@).[18]

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[16] *U.S. Healthcare, Inc.*, 986 F.2d at 598.

[17] Plaintiff has not pled a Asingle brand@ as a product market, as Aventis implies. Plaintiff includes all firms that actually or potentially supply branded and generic leflunomide, not just a single firm. Cpt. && 74-76; *see also id.* && 1, 51, 62. That is not a Asingle brand@ product market. *See Todd*, 275 F.3d at 200 n.3; *Xerox Corp. v. Media Sciences Intern., Inc.*, 2007 U.S. Dist. LEXIS 68081, *26, 26 n.7 (S.D.N.Y. Sept. 14, 2007).

[18] *See also In re Cardizem CD Antitrust Litig.*, 105 F.Supp.2d 618, 680-81 (E.D. Mich. 2000) (denying motion to dismiss allegations of a relevant market of branded and generic versions of Cardizem CD); *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 363 F.Supp.2d 514, 522-23 (E.D.N.Y. 2005) (relevant market limited to brand and generic versions of ciprofloxacin); *Schering-Plough*, 2003 FTC LEXIS 187, *56 n.47 (market including K-Dur 20 and its generic equivalents was proper); *Knoll Pharmaceuticals Co., Inc. v. Teva Pharmaceuticals USA, Inc.*, 2001 U.S. Dist. LEXIS 12999, *10-11 (N.D. Ill. Aug. 24, 2001) (Rule 12 motion denied where complaint defined relevant antitrust product market as limited to hydrocodone bitartrate/ibuprofen).

In fact, contrary to Defendants= claim that a relevant market cannot be as narrow as a brand and its generics, the Second Circuit has approved a relevant market that is even narrower -- *i.e.*, a market limited to only generic versions of a drug. In *Geneva*, the Second Circuit excluded even the branded version of the drug warfarin sodium, because the antitrust question there related to the effects of the suppression of one generic competitor (Geneva) by another generic (Barr). Since there was already a generic competing with the brand in *Geneva*, the alleged anticompetitive effect was the suppression of price competition in the market for generic versions of warfarin sodium; thus, the relevant market was properly limited to the generics.[19]

Where, as here, the conduct challenged is the suppression by a branded manufacturer of all generic competition for a particular drug, thereby forcing purchasers to buy the more expensive branded version of the drug, the relevant market is properly limited to the brand and its generic competitors for that particular drug, not a host of different drugs.

Fourth, Defendants= conclusory assertion that the relevant market must always include all products that may be used for a similar purpose has been refuted by numerous courts, including the Second Circuit. As explained above, courts have routinely accepted relevant markets limited to firms manufacturing a single drug product, even though there were other drugs that were used to treat similar conditions.[20] That is because Afunctional substitutability@ of a product with the product at issue is insufficient, by itself, to warrant inclusion of the "substitutable" product in a

[19] *See also In re Lorazepam & Clorazepate Antitrust Litig.*, 407 F.Supp.2d 74, 81-82 (D.D.C. 2006) (where a generic manufacturer allegedly precluded other generics from competing by locking up supply of active ingredient, relevant market was limited to generic versions of the drugs).

[20] *See e.g., Geneva*, 386 F.3d at 490-491, 500 (relevant market did not include other drugs that functioned as oral anticoagulants, prevented strokes, or prevented heart attacks); *Ciprofloxacin*, 363 F.Supp.2d at 522-23 (limiting relevant market to Ciprofloxacin, and excluding other antibiotics).

relevant market, "substitutable" goods are not in the same market Aunless the availability of one effectively ***limited the price*** of the other to the competitive level or something slightly above.@ Areeda and Hovenkamp & 507a at 132. Put another way, a substitute product is not in the same market if it does not exhibit significant cross-price elasticity of demand with,[21] and does not ***constrain the price*** of, the product at issue, down to the competitive level.[22]

Absent definitive proof that the other RA drugs Defendants have in mind exhibit significant, positive cross-price elasticity of demand with Arava and constrained leflunomide prices down to the levels that generic competition would (and did) cause - - which proof does not exist at this early stage of the case - - it would be *error* to include them in the relevant market with Arava and its generic equivalents.

Finally, and significantly, Defendants' relevant market arguments, at best, raise disputed issues of fact that cannot be resolved on a motion to dismiss. *See New York Jets*, 2005 U.S. Dist. LEXIS 23763, *15-16 (noting the "deeply fact-intensive" nature of relevant market determinations).

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[21]"Cross-elasticity of demand refers to the change in the demand by consumers for one product as a result of a change in the price of another product." *Hayden Pub. Co. v. Cox Broadcasting Corp.*, 730 F.2d 64, 70 n.9 (2d Cir. 1984) (citing 2 P. Areeda & D. Turner, Antitrust Law 349 (1978); L. Sullivan, Antitrust 54-44 (1977)).

[22]*See Hayden Pub. Co.*, 730 F.2d at 70 (district court committed reversible error in Aneglect[ing] the factor of cross-elasticity of demand,@ which directs that the court determine not just functional substitutability, but primarily Ahow *far* buyers will go to substitute one commodity for another@); *U.S. v Microsoft Corp.*, 253 F.3d 34, 53 (D.C. Cir. 2001) (A[t]he test of reasonable interchangeability, however, required the District Court to consider only substitutes *that constrain pricing* in the reasonably foreseeable future@) (emphasis supplied). *See also F.T.C. v. H.J. Heinz Co.*, 246 F.3d 708, 718 (D.C. Cir. 2001) (same); *Brookins v. Int'l Motor Contest Ass'n*, 219 F.3d 849, 854 (8th Cir. 2000) (same); *FTC v. Swedish Match*, 131 F. Supp.2d 151, 158-60 (D.D.C. 2000) (same); *FTC v. Staples*, 970 F. Supp. 1066, 1074-75 (D.D.C. 1997) (same); *U.S. Anchor Mfg., Inc. v. Rule Industries, Inc.*, 7 F.3d 986, 995-99 (11th Cir. 1993) (same); *United States v. Archer-Daniels-Midland Co.*, 866 F.2d 242, 248 & n.1 (8th Cir. 1989) (same).

CONCLUSION

For each of the reasons discussed above, Defendants' motion should be denied.

Dated: November 8, 2007

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CERTIFICATE OF SERVICE

I, Anne K. Fornecker, do hereby certify that on November 8, 2007, I served the foregoing PLAINTIFF LOUSIANA WHOLESALE DRUG CO., INC.'S MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS SANOFI-AVENTIS US LLC AND AVENTIS PHARMACEUTICAL INC'S MOTION TO DISMISS THE COMPLAINT FOR FAILURE TO STATE A CLAIM on the following attorneys, in the manner specified below:

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